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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/160,076 09/24/98 SCOTT

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HM22/1109

EXAMINER

WILSON, M

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

11/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/160,076

Applicant(s)
Scott et al.

Examiner
Wilson, Michael C.

Group Art Unit
1633



☒ Responsive to communication(s) filed on Aug 26, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 31-51 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 31-51 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-5, 10-13 and 19-20 have been canceled. Claims 31-51 are pending and under consideration in the instant application.

Applicant's arguments filed 9-6-99, paper number 9, have been fully considered but they are not persuasive.

Claim Objections

1. Claims 35, 44 and 50 should be amended to include the phrase --the group consisting of-- after the phrase "selected from" to recite proper Markush language. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 35, 43, 44, 49 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property, i.e., tolerogenic epitopes of pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, and histocompatibility antigen because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all DNA's that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific DNA sequences, which provide the means for practicing the invention.

3. Claims 34, 35, 43, 44, 49 and 50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 34, 35, 43, 44, 49 and 50 are directed toward tolerogenic antigens derived from pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen, myelin basic

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protein, thyroglobulin, and histocompatibility antigen because the specification does not teach any epitopes derived from such entities which are tolerogenic or the nucleic acid sequences encoding such epitopes. While the clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, and histocompatibility proteins and nucleic acid sequences encoding such proteins were known at the time of filing, it was not known which epitopes were "tolerogenic" as claimed. The specification does not teach any tolerogenic epitopes of clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin or histocompatibility proteins. It is also not clear from the specification how clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, and histocompatibility antigens are "autoantigens" because the term is not defined in the specification and does not have an art recognized meaning. Regarding pollen, ragweed and dust mites, these substances were known allergens, but are made up of more than just protein; therefore, it is unclear what applicants intend to claim. The specification does not teach any antigens of pollen, ragweed or dust mites, provide the nucleic acid sequence of such allergens or teach any tolerogenic epitopes derived from pollen, ragweed or dust mites as claimed. Dust mites and ragweed are whole organisms while pollen is a substance found in any plant. It would require one of skill to determine the tolerogenic epitopes of the exceedingly numerous proteins found in any pollen, ragweed or dust mite. The specification does not provide adequate guidance to transform cells with a vector encoding epitopes from pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen,

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myelin basic protein, thyroglobulin, and histocompatibility antigen such that the epitopes are tolerogenic as claimed.

Therefore, in view of the lack of guidance in the specification regarding how to isolate a nucleic acid sequence encoding a tolerogenic epitope from pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin or histocompatibility antigens, the state of the art, the examples provided and the breadth of the claims, the ordinary artisan at the time of the instant invention would not have known how to make and/or use the claimed invention with a reasonable expectation of success.

4. Claims 31-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 41 and 47 and claims dependent therefrom are indefinite because it is unclear which preceding element the term "functional" in line 4 refers. In line 6, the phrase "said fusion immunoglobulin" lacks antecedent basis in the claim. The phrase "derived" is indefinite because the term is not defined in the specification and may have various meanings in the art. It is unclear whether the epitope is isolated from an antigen or has a function similar to the antigen. The phrase "to which tolerance is to be induced" is confusing. If the phrase refers to an antigen to which tolerance is to be induced, it is unclear what characteristics the antigen possess. Are applicants intending to claim an antigen which can induce tolerance? If the phrase refers to tolerance to be induced in the N-terminal variable region, it is unclear what applicants intend to

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claim. The phrase "associated with" found also in claims 34, 42, 43, 48 and 49 is indefinite because the phrase is not defined in the specification and may have various meanings in the art. It is unclear whether applicants intend to claim an antigen which is a cause of disease or allergic reaction or which is a result of disease or allergic reaction. The term may also mean a physical association or bond which is not possible between an antigen and a disease or allergic reaction.

Claim 32 is indefinite because the phrase "the heavy chain" is unclear. Claim 32 is dependent upon claim 31 which may encode a heavy or light chain. Since the vector of 31 may not include the heavy chain and claim 32 does not limit the claim to the heavy chain, it is unclear how to have a vector expressing an epitope next to the heavy chain as claimed.

Claim 34, 43 and 49 are indefinite because the claim requires the epitope is derived from an antigen wherein said antigen is an antigen of pollen, ragweed or a dust mite. However, ragweed and dust mites are whole organisms. Antigens are not derived from whole organisms. Antigens are derived from proteins. Likewise, pollen is made up of more than just protein. It is unclear whether applicants intend to claim antigens derived from proteins within these organisms or antigens derived from a non-protein which causes an immune response which is found within these organisms.

Claims 35, 44 and 50 are indefinite because the term "autoantigen" because an antigen that is recognized as a "self-antigen" in one person may not be recognized as "self-antigen" in a different person. The term "autoantigen" is not defined in the specification and does not have an art recognized meaning; therefore, the term is indefinite. The term "histocompatibility antigen" is

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indefinite. It is unclear whether applicants intend to claim a particular epitope derived from a histocompatibility molecule such as B7 or whether applicants intend to claim an epitope derived from a protein involved in histocompatibility such as antibodies involved in tolerance.

Claim 38 is indefinite because the term "characteristics" is not defined in the specification and may have various meanings in the art as stated in the previous office action. It is unclear whether applicants intend to claim a physical characteristic or a function.

Double Patenting

5. The rejection of claims 31-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 5,817,308 (Application 08/195874), 10-6-98 is withdrawn in view of the restriction requirement set forth on 8-6-96, paper number 17, in parent case 08/195874.

Claim Rejections - 35 USC § 102

6. Claims 31, 32, 37, 39, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Zambidis et al. (Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251) for reasons of record set forth in the office action of 5-11-99, paper number 7 as applied to claims 1, 3-5, 10-13, 19 and 20.

Applicants argue the newly added claims are not anticipated by Zambidis et al. because Zambidis et al. do not teach an antigen which is associated with an autoimmune disease or allergic

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reaction. Applicants argument is not persuasive because of the indefiniteness rejection regarding the phrase "associated with". The claim encompasses autoimmune disease or allergic reaction induced by bacteria. Specifically, the disease or reaction may be "associated with" the bacteriophage λ cl protein. The λ cl protein is a foreign protein to animals and would be recognized by the immune system and an immune reaction would occur. Since an immune reaction to a foreign protein is equivalent to an allergic reaction, the λ cl protein meets the limitation of the claim. Therefore, Zambidis et al. anticipates the claims as written by teaching the bacteriophage λ cl protein placed at the N-terminus of the IgG1 heavy chain and J588L cells transformed by said construct (see entire abstract). As J588L cells are a myeloma cell line which is a bone marrow tumor cell line, Zambidis et al. clearly anticipates claims 39 and 40. Applicants state the claims in the previous application overcame Zambidis et al. because Zambidis et al. did not teach obtaining tolerance. The claims in the parent application were directed toward methods of inducing tolerance while the instant claims are directed to vectors and cells. The intended use of tolerance as written in the instant claims bears little patentable weight when considering art rejections because the intended use does not change the composition of the claims.

Claim Rejections - 35 USC § 103

7. Claims 31-33, 36, 37, 39-42, 45-48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zambidis et al. (Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251) in view of Zanetti et al. (Jan. 30, 1992, Nature, Vol. 355, pages 476-477) and

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Chambers et al. (Feb. 1992, PNAS, USA, Vol. 89, pages 1026-1030) for reasons of record as set forth in the office action of 5-11-99, paper number 7 as applied to claims 1-5, 10-13, 19 and 20.

Zambidis et al. teaches a construct comprising residues of the bacteriophage λ cl protein placed at the N-terminus of the IgG1 heavy chain and J588L cells transformed by said construct (see entire abstract). Zambidis et al. do not teach using a retroviral vector. However, at the time of filing, Chambers et al. teach expressing lymphokines in peripheral blood lymphocytes (PBL) using a retroviral construct encoding the b-actin promoter/enhancer (page 1029, column 2, "discussion"). Motivation to combine the references is provided by Chambers et al. because the retroviral vector of Chambers et al. is an improved method of transfecting reproducing cells such as lymphoid or hemopoietic cells as claimed which would have been recognized by one of ordinary skill in the art at the time of filing. One of ordinary skill would have recognized the ability to improve transduction in lymphoid cells using the retroviral vector and to express the fusion protein in lymphoid cells to study the immune system which was common at the time of filing. The expression of proteins in T-cells and PBLs as taught by Zanetti and Chambers et al. also indicates the transcriptional and translational control regions function in lymphoid cells as claimed providing one of ordinary skill with a reasonable expectation of success.

Applicants argue Zambidis et al. does not provide a reasonable expectation of success and should not be used in the 103 rejection. Applicants argument is not persuasive as is discussed above in the response to arguments presented in the 102 rejection above. Applicants request clarification why Zanetti et al. was used in the previous office action. Zanetti et al. supports the

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expression of proteins in T-cells and PBL and supports examiners position that one of skill would have a reasonable expectation of success in obtaining the vectors and cells claimed.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

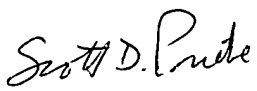
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Michael C. Wilson


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER